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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,354	03/31/2004	Rajesh V. Mehta	86430AJA	7757

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EXAMINER	
DRODGE, JOSEPH W	

ART UNIT	PAPER NUMBER
1723	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,354	MEHTA ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The drawing (figure 9) was received on June 8, 2007. These drawings are acceptable.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saim et al patent 6,858,166 in view of Johnson et al PGPUBS Document US2004/0091546 and O'Conner et al PGPUBS Document US2006/0124783.

Saim et al disclose formation of micro or nano-particles by a process of admitting a supercritical fluid to a vessel, in which temperature and pressure are controlled (column 14, lines 21-45), agitating such vessel with a rotary agitator that may comprise an impeller of un-specified, given diameter relative to vessel diameter (column 14, line 63-column 15, line 6), introducing a 1st feed stream comprising a solvent and desired, active substance through a 1st introduction port and introducing a 2nd feed stream comprising the supercritical fluid through introduction ports both approximately within the highly agitated zone of the mixer that may be an impeller (see especially figures 1 and 2 and column 18, lines 30-63). ***The rotary impeller agitator inherently agitates material in the immediate vicinity therein at a more agitated, faster rate than material at progressive more distant locations from the impeller surfaces***. Both a first feed stream including particle-forming components and solvent and a second feed stream containing the supercritical fluid may be introduced proximate the agitated/highly agitated zone of the mixer (see column 12, lines 11-12 taken with lines 33-36 of column 12). Particles are then precipitated within such vessel over a carrier bed. A major use of the Saim process is to produce a wide variety of pharmaceutical particles (column 6, lines 42-53). ***Regarding inlet locations, a carrier bed may be formed by mixing carrier material with agitated, precipitated particles formed in the vessel (column 9, lines 43-49), and the zone of carrier material may cover any portion or the***

entirety of the vessel, with both the first stream of solvent and substance and second stream of supercritical fluid, or other gaseous or liquid solution, introduced anywhere within the carrier bed or above the carrier bed (column 12, lines 8-36 and column 13, lines 14-30, also column 15, lines 15-22).

The impeller or other agitator of the mixing vessel may be controlled to rotate at very high rotational speeds, so as to obtain high stirring intensity with vigorous stirring, hence induce turbulent mixing (column 12, lines 21-24, column 13, lines 50-51 and column 14, lines 30-32 and 62-65). ***Various forms of impeller and similar blades including pitched, curved, flat and helical designs may be employed in agitating. Column 15, lines 3-5 also states that plural "mixing devices may be employed".*** Temperatures, pressures and other parameters are controlled to obtain optimum performance (column 11, line 57-column 12, line 2). Precipitated particles are formed to be of nanoparticle size, hence inherently of a volume-average diameter in the range of 100 nanometers or less (column 17, lines 5-8 and 54-67). ***Also column 9, lines 43-49 states that particles having diameters as small as .001 micron (1 micron), or well within the claimed range of "smaller than 20 microns) may be formed. The vessel inherently facilitates more rapid and more turbulent mixing in the immediate vicinity of the impeller agitators grading to less rapid and less turbulent/ bulk mixing in zones further away from the impeller.***

The claims differ in requiring an explicit teaching of the particle formation and agitating vessel containing the impeller having two discrete mixing zones. However,

O'Connor et al teaches to produce nanoparticles using solvents and supercritical fluids by use of conversion/mixing vessels that combine impeller mixers with other type stirrers, that have inlets for introducing solvents and other materials, and/or have a plurality of impeller mixers or impellers with differently functioning blades so as to create different mixing zones of different degrees of turbulence. See especially paragraph 33 and paragraphs 22-32 and 38-40 are also pertinent. It would have been obvious to one of ordinary skill in the art to have adapted the more-complex configuration of mixing/agitating means of O-Connor in the process of Saim et al, or to have recognized the effect of thaving a plurality of mixing devices in creating different mixing zones, to effect greater, more complete mixing of components which are in slurry form, or mixing of materials of different phases (liquids, solids, semi-solids and gases).

The claims also differ in requiring the feed stream introduction ports to be located within one impeller diameter of the surface of the impeller agitator. However, Johnson et al teach production of nanoparticles using supercritical fluid processing in which the inlet tubes are within 15% of the agitator surface diameter (see especially paragraph 44, paragraphs 39-42,58 and 63 are also quite germane). ***In paragraph 17, Johnson states that solvent streams are advantageously located to introduce material "in a region near a mechanical agitator, where the mixing velocity is most easily controlled. Paragraph 58 of Johnson confirms that supercritical fluid may be introduced during the process of nanoparticle formation. Paragraph 66 additionally relates Johnson to Saim in stating that supplemental seed molecules***

may be used to facilitate the creation of nanoparticles upon micromixing and that such seed material may comprise pharmaceutically acceptable carrier material.

It would have been further obvious to one of ordinary skill in the art to have located the end of the inlet tubes of Saim et al very close to the impeller agitators as suggested by Johnson et al, to facilitate rapid incorporation of the incoming fluid into the swept region of the agitator and rapid mixing, and to have more readily controlled mixing velocity so as to achieve result of better control of size range of formed nanoparticles.

Regarding dependent claims, Saim also discloses the following: for claims 3,7 and 6, flow of particles exhausted to an expansion or collection chamber that may constitute a distributor (column 21, lines 10-17), use of capillaries for claim 5 (column 13, line 15), for claim 8 forming of a dispersion (column 6, line 34), for claims 9-14 forming of nanosize particles of relatively uniform particle size (column 17, lines 5-8 and column 7, lines 6-8), and for claims 15-18 forming of a wide range of pharmaceutical and industrial particles including the instantly claimed species (column 16, lines 33-45); paragraph 42 of O'Connor is also quite pertinent to claims 15-18.

Regarding claims 2 and 4, Saim discloses a steady-state operation of processing and agitation in the mixing/processing vessel (paragraph 14, lines 46-50) and illustrates a back-pressure regulator in the outlet from the processing vessel at the Mode 2 illustration of Figure 1. Also paragraph 42 of Johnson describes a steady-state

operation with a maintained flow balance between incoming streams and collected streams.

Applicant's arguments filed on June 8, 2007 have been fully considered but they are not persuasive. It is argued that it is not obvious to have combined the original teachings of Saim et al, O'Conner and Johnson since they employ distinct types of materials and apparatus for diverse purposes. This is addressed by stating that all 3 references are commonly directed to production of nanoparticles by solvent extraction, supercritical fluid processing and precipitation processes. Other links have been indicated in the preceding rejection on the merits between similar types of mixing blades and mixing device designs of the impeller mixers of Saim et al and O'Conner, and employ of similar supercritical fluid processing and use of seed and carrier material between Saim et al and Johnson. The combining of processes / apparatus components of O'Conner and Johnson only incrementally modifies the basic system and process of Saim et al; Saim when considered in its entirety discloses a process and system substantially similar to that of the instant claims.

It is argued that the inlets or introduction points of Saim are distinctly different from those claimed , pressurized gaseous fluid only introduced from above the upper surface of bed of carrier materials. However, Saim does not substantially limit introduction points for the feed streams, for instance column 15, lines 17-22 indicates gaseous fluid solution or liquid solution being introduced at any point within or above the zone of carrier material.

It is contended that O'Conner among the applied art is uniquely directed to particle size reduction. However, all 3 references are also directed to reducing size of particles , however Saim also atomizes particles or otherwise reduces their size during the process (column 13, second parargraph , column 14, lines 53-55).

It is asserted that Johnson teaches that agitators are only optionally utililized. However, Johnson at paragraph 44 states that agitators are used in a preferred embodiment to advantageously achieve high mixing intensity.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Roy Sample, can reached at 571-272-1376. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

July 15, 2007

JOSEPH DRODGE
PRIMARY EXAMINER